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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,720	04/30/2001	Qun Wei	2033.000	3724

7590 12/16/2004

GEHRKE & ASSOCIATES S C
123 North 86th Street
Wauwatosa, WI 53226

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,720	WEI ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: 3 pages of Sequences.

DETAILED ACTION

Current Application Status

The Change in the Power of Attorney filed on May 19, 2004 is acknowledged and has been entered. Claims 1-8 are pending in the application and are currently under consideration.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Although, the instant application has been accepted under U.S.C. 371, it does not appear that the Oath and Declaration filed on 2/23/2001 has been signed.

Specification

The specification is objected to (page 6, lines 18-21, page 7 lines 21 and 22, and page 8, line 26) for improper disclosure of amino acid and nucleotide sequences without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 are rejected as vague and indefinite for reciting the term CaN subunit B in as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a

particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify CaN subunit B, for example, by SEQ ID NO. and function of CaN subunit B.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of molecules possessing CaN B function. However, the written description in this case only sets forth one CaN B molecule consisting of the amino acid sequence set forth shown on page 6, lines 18-21.

The specification teaches (page 7, lines 15-18) that specific CaN B molecules of the invention include, but are not limited to, any compounds which retains the biological activity of CaN subunit B. The specification teaches (page 6, lines 23-27) that this includes not only CaN subunit B shown on page 6, lines 18-21, but any derivatives obtained by addition, deletion, substitution of one or more amino acids in the above mentioned sequence, or the functional derivative obtained by chemical modification of the side chains of one or more of the amino acids. With regards to the biological activity of the CaN subunit B, the specification teaches (page 7, lines 1-3) that the CaN subunit B can accelerate the augmentation of spleen demonstrating its importance as an excellent immune upward regulation agent or an excellent biological response regulator. However, the specification appears to be silent on any other molecule possessing CaN B function. Thus, the written description only sets forth one species of CaN subunit B (shown on page 6, lines 18-21) possessing the function of up regulating the immune response; and therefore, is not commensurate with the full scope of any and all derivatives of CaN subunit B possessing CaN B

function. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of molecules/derivates of CaN B that encompass the genus of molecules that possess CaN B function nor does it provide a description of structural features that are common to the molecules. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species of CaN B is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only one CaN B molecule consisting of the amino acid sequence set forth shown on page 6, lines 18-21, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Aitken *et al.* (Eur. J. Biochem. 1984, 139; 663-671).

In the instant case, the claims are drawn to a composition for treatment of mammal diseases, comprising an effective amount of CaN subunit B or its derivatives possessing CaN B function. The claims are further drawn to wherein the treatment is achieved by regulating the immune system of the mammal, the composition contains a pharmaceutically acceptable carrier or excipient, the mammal disease to be treated is a disease which can be treated by regulating the immune response of the mammal or is cancer, the mammal is either human or mouse. Further, the claims are drawn to the use of CaN subunit B for the manufacture of medicament for the treatment of mammal disease.

Aitken *et al.* teach (page 669, Figure 3, see attached) a purified protein having an amino acid sequence which appears to be identical to the claimed CaN subunit B. The reference further discloses (page 664, Fig. 1) a solution of the protein in 0.05M ammonium bicarbonate. Although the reference does not specifically teach that the purified peptide regulates the immune system or treats cancer, the claims are drawn to the product *per se* and inherently, such a polypeptide would

regulate the immune system or treat cancer. The intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman *et al.* (U.S. 6,093565, 1996).

The claims are drawn to a composition for treatment of mammal diseases as described above for claims 1-6. In addition, the claims are drawn to the use of CaN subunit B for the manufacture of medicament for the treatment of mammal disease.

(Note: For the purposes of comparing the claims to the prior art, it is assumed for examination purposes that CaN is calcineurin. The specification teaches (page 1, line 7) that CaN is short for calcineurin.)

Hillman *et al.* disclose (column 1, lines 5-9) an amino acid sequence of a novel protein phosphatase and its use for the diagnosis, prevention, and treatment of immunological diseases, neurological disorders, and cancer. Specifically, the patent provides (column 3, lines 19-22) a novel protein phosphatase having similarity to the calcineurin B protein phosphatase regulatory subunit from Naegleria gruberi, mouse testis, and human brain. Hillman et al. further teach (column 20, lines 37-40) that the method can be applied to any subject in need of such therapy, including for example, mammals such as humans and that the effective does can be estimated initially in animal models such as mice (column 22, lines 19-22). In addition, the patent provides (column 20, lines 60-64) the preparation of pharmaceutical compositions containing pharmaceutically acceptable carriers comprising excipients and auxiliaries.

Therefore, NO claim is allowed.

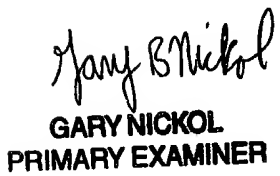
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF



Sent to applicant

RESULT 2
S34127

R;Aitken, A.; Klee, C.B.; Cohen, P.
Eur. J. Biochem. 139, 663-671, 1984
A;Title: The structure of the B subunit of calcineurin.
A;Reference number: JT0297; MUID:84132092; PMID:6321184
A;Accession: JT0297
A;Molecule type: protein
A;Residues: 2-11,'M',13-153,'S',155-169 <AIT>

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Send to applicant


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US-08-764-563-5
; Sequence 5, Application US/08764563
; Patent No. 6093565
;  GENERAL INFORMATION:
;    APPLICANT:  Hillman, Jennifer L.
;    APPLICANT:  Goli, Surya K.
;    TITLE OF INVENTION:  A NOVEL PROTEIN PHOSPHATASE
;    NUMBER OF SEQUENCES:  5
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Incyte Pharmaceuticals, Inc.
;      STREET:  3174 Porter Drive
;      CITY:  Palo Alto
;      STATE:  CA
;      COUNTRY:  USA
;      ZIP:  94304
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Diskette
;      COMPUTER:  IBM Compatible
;      OPERATING SYSTEM:  DOS
;      SOFTWARE:  FastSEQ for Windows Version 2.0
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/764,563
;      FILING DATE:  Herewith
;      CLASSIFICATION:  514
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:
;      FILING DATE:
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Billings, Lucy J.
;      REGISTRATION NUMBER:  36,749
;      REFERENCE/DOCKET NUMBER:  PF-0178 US
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  415-855-0555
;      TELEFAX:  415-845-4166
;      TELEX:
;  INFORMATION FOR SEQ ID NO:  5:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  170 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:  single
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;    IMMEDIATE SOURCE:
;      LIBRARY:  GenBank
;      CLONE:  461682
US-08-764-563-5

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